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09/445,796	03/13/2000	DOMINIQUE BRASSART	P99.2625	1391

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EXAMINER

AFREMOVA, VERA

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 05/09/2003

26

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 09/445,796	Applicant(s) Brassart et al.
Examiner Vera Afremova	Art Unit 1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM

THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on Apr 9, 2003

2b) This action is non-final.

2a) This action is FINAL.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-14, 16-19, and 21-26

is/are pending in the application.

5) Claim(s) _____ is/are withdrawn from consideration.

4a) Of the above, claim(s) _____

is/are allowed.

5) Claim(s) _____

is/are rejected.

6) Claim(s) 1-14, 16-19, and 21-26

is/are objected to.

7) Claim(s) _____

are subject to restriction and/or election requirement.

8) Claims _____

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

4) Interview Summary (PTO-413) Paper No(s). _____

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). 25

6) Other: _____

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/09/2003 has been entered.

Status of claims

Claims 11-14, 16-19 and 21-26 as amended [Paper No. 24 filed 4/09/2003] are pending and under examination in the instant office action.

Claims 1-10 were canceled by applicants in the Paper No. 10 filed 6/04/2001.

Claims 15 and 20 were canceled by applicants in the Paper No. 20 filed 9/03/2002.

Deposit

The deposit requirement for *Lactobacillus johnsonii* CNCM I-1225 has been met in the Paper No. 10 filed 6/04/2001.

Claim Rejections - 35 U.S.C. § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 11-13, 16-19, 21-25 as amended remain rejected under 35 U.S.C. 102(b) as being anticipated by US 5,578,302 [B] as explained in the prior office action and for the reasons below.

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Claims 11-14, 16-19 and 21-26 as amended remain rejected under 35 U.S.C. 102(b) as being anticipated by US 5,494,664 [A] as explained in the prior office action and for the reasons below.

The claims are directed to methods for treatment or prophylaxis of calcium deficiencies in a mammal or for improving absorption of calcium from the diet wherein the methods comprise a step of enterally administering to a mammal having calcium deficiency or at risk of calcium deficiency or requiring increased calcium absorption a nutritional composition comprising one or more live *Lactobacillus* bacteria. Some claims are further drawn to the use of *Lactobacillus sp.* CNCM I-1225 which is capable of adhering to intestinal cells in the method of administration of the nutritional composition. Some claims are further drawn to the use of milk products and/or milk hydrolysates in the nutritional composition in the method of administration. Some claims (14 and 26) are further drawn to the use of lactobacteria in amounts 10^7 to 10^{11} CFU/ml in the method of administration of the nutritional composition.

The cited US 5,578,302 [B] and US 5,494,664 [A] are relied upon as explained in the prior office action and repeated herein.

US 5,578,302 [B] (abstract) teaches a method for improving mammal health wherein the method comprises enterally administering to a mammal a nutritional composition which contains live bacteria belonging to the genus *Lactobacillus* including particular strain *Lactobacillus johnsonii (acidophilus)* CNCM I-1225 (col. 2, line 13) in nutritional composition in a form of yogurt or milk-based powdered formulations (col.1, lines 43-44).

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US 5,494,664 [A] (col. 1, line 43-60 and col. 2, line 14) teaches a method for improving mammal health wherein the method comprises enterally administering to a mammal a nutritional composition which contains live lactobacteria and/or bifidobacteria including *Lactobacillus acidophilus (johnsonii)* CNCM I-1225 in amounts 10^7 to 10^8 CFU/ml in nutritional composition in a form of yogurt or other milk-based product.

The cited patents are considered to anticipate the claimed invention because the methods of the cited patents are one active step methods which comprise an identical step of enterally administering identical patients such as mammalian patients an identical composition comprising identical bacteria belonging to the genus of *Lactobacillus* or strain CNCM I-1225 belonging to the species of *Lactobacillus johnsonii* (previously identified as *acidophilus*) which is capable of adhering to intestinal cells. All mammalian patients are in need of calcium absorption for maintaining bone tissues and/or general healthy state and, thus, the mammalian patients of the cited references are considered to be identical to the patients in the claimed method who are having calcium deficiency or at risk of calcium deficiency within the meaning of the claims. Consequently, the results of practicing identical protocols of administering are reasonably expected to be identical. The methods of the cited patents comprise the use of compositions with milk ingredients as well as ingredients of whole live cell preparations derived from one or more *Lactobacillus* bacteria as the claimed method, and, thus, administration of identical compositions with identical components as claimed are reasonably expected to inherently provide mammalian patients with benefits related to treatment or prophylaxis of

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calcium deficiencies or for improving absorption of minerals including calcium from the diet as intended for the claimed method. Moreover, the method of US 5,494,664 [A] teaches the use of nutritional compositions with the same amounts of the same bacterial strain CNCM I-1225 as the claimed method. Therefore, identical benefits are inherent to the identical administration.

Therefore, the methods are identical as disclosed and as claimed.

With regard to the cited patents applicants argue that they do not teach or suggest the beneficial effects such as calcium absorption from diet as result of oral administration of live lactobacteria (response page 5, par. 3). However, the identical benefits are inherent to the identical administration as explained above.

In order to qualify as an anticipatory reference, the disclosure need not be express. Even failure of those skilled in the art to contemporaneously recognize an inherent property, function or ingredient of a prior art reference does not preclude a finding of anticipation: In *Atlas Powder Co. v. IRECO, Inc.*, 51 USPQ2d 1943 (Fed. Cir. 1999). Thus, applicants are incorrect in arguing that the anticipatory rejection is improper and must teach the intended effect.

"To invalidate a patent by anticipation, a prior art reference normally needs to disclose each and every limitation of the claim. See *Standard Havens Prods., Inc. v. Gencor Indus., Inc.*, 953 F.2d 1360, 1369, 21 USPQ2d 1321, 1328 (Fed. Cir. 1991). However, a prior art reference may anticipate when the claim limitation or limitations not expressly found in that reference are nonetheless inherent in it. See *id.*; *Verdegaal Bros., Inc. v. Union Oil Co. of Cal.*, 814 F.2d 628,

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630, 2 USPQ2d 1051,1053 (Fed. Cir. 1987). Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates.

Applicants argue that there is a number of reasons why a mammal would require increased mineral absorption such as pregnancy or old age (see response page 5, last par.) Thus, applicants appear to argue that the patients under treatment with live lactobacteria are different in the claimed method and in the methods of the cited patents. However, the mammalian patients which are regarded by applicants as patients in the method of the present invention include a broad range of patients from young children to mature and elderly people (see abstract). Thus, the patients of the present invention are normal patients who are not diagnosed with severe calcium deficiencies. Moreover, the particular applicants' example demonstrates an *in vitro* method involving the use of an adenocarcinoma cell line as a model for calcium absorption in the presence of lactobacteria rather than the *in vivo* method comprising treatment of the patients as argued. Thus, the mammalian patients including humans in the methods of the cited patents are the same patients as encompassed by the present invention within the meaning of the claims and in the light of as-filed specification since all mammalian patients are in need of calcium absorption from the diets for the purpose of prophylaxis or treatment of calcium absorption from the diets and for maintaining general healthy state.

Applicants appear to argue that the method of the cited patents do not teach administration of lactobacteria capable to arrive in living state to the intestines of mammals (response page 6, par. 2). However, the bacterial strain *Lactobacillus acidophilus (johnsonii)*

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CNCM I-1225 which is administered in the methods of the cited patents is identical to the claimed strain in the claimed method. Thus, the identical bacterial strain which is administered in a living state as a live bacterial preparation is reasonably expected to exhibit identical properties including capability to arrive in living state to the intestines within the meaning of the claims. The applicants' argument with regard to direct interaction of living bacterial cells and intestinal cells (response page 6, par. 3) is drawn to a mechanism of action, which is an inherent event in identical processes, rather than to the differences in the active steps and/or structural elements in the methods as presently claimed and as disclosed by the cited patents.

Claim Rejections - 35 U.S.C. § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 11-14, 16-19 and 21-26 as amended remain rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,578,302 [B] or US 5,494,664 [A] taken with Yaeshima [IDS-3-AR] and Sellars [U-19] as explained in the prior office action and for the reasons below.

The claims are directed to methods for treatment or prophylaxis of calcium deficiencies in a mammal or for improving absorption of calcium from the diet wherein the methods comprise a step of enterally administering to a mammal at risk of calcium deficiency a nutritional composition comprising one or more live bacteria belonging to the genus of *Lactobacillus* bacteria. Some claims are further drawn to the use of particular strain CNCM I-1225 belonging to *Lactobacillus johnsonii* (priorly identified as *acidophilus*) which is capable of adhering to

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intestinal cells in the method of administration of the nutritional composition. Some claims are further drawn to the use of milk products and/or milk hydrolysates in the nutritional composition in the method of administration. Some claims are further drawn to the use of bacteria in amounts 10^7 to 10^{11} CFU/ml in the method of administration of the nutritional composition.

The cited patents US 5,578,302 [B] or US 5,494,664 [A] are relied upon as explained above for the disclosure of the methods of administering nutritional compositions comprising live bacteria belonging to the genus of *Lactobacillus* including particular strain CNCM I-1225 *Lactobacillus johnsonii* (previously identified as *acidophilus*) which is capable of adhering to intestinal cells. The cited methods clearly teach health improvement in the health of mammals as the result of administering compositions with various lactobacteria including bacteria that which are presently claimed. However the cited patents are silent with regard to particular effects related to treatment or prophylaxis of calcium deficiencies in mammal or for improving absorption of calcium from the diets.

However, the reference by Yaeshima [IDS-3-AR] teaches method for treatment and/or improving mineral absorption including calcium absorption by administering live lactobacteria to mammals, for example: see page 41, col. 1-2 or Fig. 13., wherein the method comprises enterally administering to a mammal a nutritional composition with live lactobacteria including representatives of the genus *Bifidobacterium* alone or with additional products such as dietary fibers (oligosaccharides or lactulose) and minerals (calcium, magnesium, etc.). The cited

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reference clearly teaches that oral consumption of lactobacteria promotes calcium absorption and increases bone strength (page 41, col. 2, par. 1.).

Further, the reference by Sellars [U-19] teaches that the acidophilus products which are known to comprise representatives of bacterial genera *Lactobacillus* and/or *Bifidobacterium* including representatives of bacterial species *Lactobacillus acidophilus* (see tables I-III at pages 84-86) exhibit health promoting properties associated with establishment of an acidophilus microflora in mammals and increased mineral absorption (page 100, par. 3 and page 102, par. 2).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to use live lactobacteria belonging to the genus *Lactobacillus* or to the strain CNCM I-1225, which is *Lactobacillus johnsonii* (priority identified as *acidophilus*), in the method of administering to mammals with a reasonable expectation of success in treating mineral deficiencies including calcium deficiency in mammals and/or improving absorption of minerals including calcium from diets because consumption of acidophilus products comprising various lactobacteria including bacteria belonging to *Lactobacillus* and/or *Bifidobacterium* or including bacteria belonging to the species of *Lactobacillus acidophilus* have been taught and suggested in the prior art for promoting mammalian health including health benefits such as increasing mineral absorption including calcium absorption from diets. Further, it is considered to be within the skills of an ordinary practitioner in the field to adjust amounts and components of the nutritional compositions intended for treatment or prophylaxis of mineral deficiencies including calcium deficiencies or for improving absorption of calcium from diets depending on

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patient age, life style and/or general state of health. Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

With regard to the claim rejection under 35 U.S.C. § 103 applicants argue that the secondary references do not remedy the deficiencies of the cited patents US 5,578,302 [B] or US 5,494,664 [A] and they do not suggest capability of lactobacteria for improving absorption of calcium from the diets (response pages 7-8).

First, the applicants' argument (response page 7) with regard to direct interaction of living bacterial cells and the intestinal cells is drawn to a mechanism of action which is based on the applicants' *in vitro* model which is not the presently claimed subject matter.

Further, the secondary references clearly demonstrate the effects associated with improved mineral absorption including calcium absorption as result of oral administration of live lactobacteria in acidophilus products including representatives of *Lactobacillus acidophilus* as explained above.

In particular, with regard to the cited reference by Sellars [U-19] applicants appear to argue that it does not teach the criticality of a direct interaction between lactic bacteria and intestinal cells. However, this is not the presently claimed subject matter and in response to applicants' argument it is noted that the features upon which applicant relies (i.e., calcium

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absorption by intestinal cells) are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The particular disclosure (specification page 9) which appears to be relied upon in the arguments (response page 7) demonstrates the *in vitro* model of calcium absorption by intestinal cells Caco-2 derived from adenocarcinoma. The claimed method is directed to administration of a product comprising live lactic bacteria for the intended benefit in improving calcium absorption from diets. The reference by Sellars clearly teaches that the acidophilus products which are known to comprise representatives of bacterial genera *Lactobacillus* and/or *Bifidobacterium* including representatives of bacterial species *Lactobacillus acidophilus* (see tables I-III at pages 84-86) exhibit the health promoting properties associated with establishment of an acidophilus microflora in mammals and increased mineral absorption which includes calcium absorption.

With regard to the cited reference by Yaeshima [IDS-3] applicants appear to argue that it teaches effects of bacteria identified as belonging to the genus of *Bifidobacterium* and, thus, the cited bacteria belong to a non-related gender (response page 8, last par.). However, both bifidobacteria including representatives of genus *Bifidobacterium* and lactobacillus including representatives of genus *Lactobacillus* belong to the same group of beneficial lactic bacteria which are common components of acidophilus products wherein the benefits of the lactic bacteria include improved mineral absorption or calcium absorption. Thus, the bacterium such as

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Bifidobacterium of the reference by Yaeshima is a bacterium similar to the claimed bacterium *Lactobacillus* with regard to the intended effects in the method of administration.

The claim rejection over the reference by Yosida [U] has been withdrawn as redundant teaching.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (703) 308-9351. The examiner can normally be reached on Monday to Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vera Afremova

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May 7, 2003

VERA AFREMOVA

PATENT EXAMINER

V. Afremova